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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,602	12/12/2003	Hao-Jan Lin	JCLA10516	1741
23900 J C PATENTS	7590 06/12/2 , INC.	007	EXAM	INER
4 VENTURE, SUITE 250				DANIEL M
IRVINE, CA 9	2018		ART UNIT	PAPER NUMBER
			1636	
			MAIL DATE	DELIVERY MODE
			06/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No.	Applicant(s)		
		10/735,602	LIN ET AL.		
Office Action Summary		Examiner	Art Unit		
	·	Daniel M. Sullivan	1636		
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet w	ith the correspondence address		
A SH WHIC - External after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATE of time may be available under the provisions of 37 CFR 1.11 SIX (6) MONTHS from the mailing date of this communication. Deperiod for reply is specified above, the maximum statutory period vere to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNI 36(a). In no event, however, may a will apply and will expire SIX (6) MOI cause the application to become A	CATION. reply be timely filed NTHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133).		
Status					
1)	Responsive to communication(s) filed on 19 M	<u>arch 2007</u> .			
2a) <u></u> □	This action is FINAL . 2b)⊠ This action is non-final.				
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
	closed in accordance with the practice under E	x parte Quayle, 1935 C.E). 11, 453 O.G. 213.		
Dispositi	ion of Claims	·			
5)□ 6)⊠ 7)□	Claim(s) <u>1-15</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdraw Claim(s) is/are allowed. Claim(s) <u>1-15</u> is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or	vn from consideration.			
Applicati	ion Papers				
10)	The specification is objected to by the Examine The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex	epted or b) objected to drawing(s) be held in abeyar ion is required if the drawing	nce. See 37 CFR 1.85(a). g(s) is objected to. See 37 CFR 1.121(d).		
Priority u	ınder 35 U.S.C. § 119				
a)[Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureausee the attached detailed Office action for a list	s have been received. s have been received in A ity documents have been i (PCT Rule 17.2(a)).	Application No I received in this National Stage		
		•			
Attachmen 1) Notic	t(s) e of References Cited (PTO-892)	4) Interview S	Summary (PTO-413)		
2) Notic 3) Inform	te of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date	Paper No(s)/Mail Date nformal Patent Application		

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DETAILED ACTION

This Office Action is a reply to the Paper filed 19 March 2007 in response to the Final Office Action mailed 18 October 2006. Claims 1-15 were considered in the 18 October Office Action. Claims 1, 9, 11 and 14 were amended in the 19 March Paper. Claims 1-15 are pending and under consideration.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 March 2007 has been entered.

Response to Amendment and Arguments

Claim Rejections - 35 USC § 102

Rejection of claims 1-8, 10-13 and 15 under 35 U.S.C. 102(b) as being anticipated by Bellhouse et al., 1994, WO 94/24263 was **withdrawn** in the 18 October Office Action.

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Claim Rejections - 35 USC § 103

Rejection of claims 1-15 under 35 U.S.C. 103(a) as being unpatentable over Bellhouse et al. (WO 94/24263, of record, hereinafter Bellhouse) in view of Bhat et al. (J. Appl. Genet. 2001, 42(4): 405-412, hereinafter Bhat) is **withdrawn** in view of the amendments and arguments presented in the 19 March Paper.

New Grounds

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a <u>new matter</u> rejection.

The MPEP states, "[i]f new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. §112, first paragraph-written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." (MPEP § 2163.06). The MPEP further states, "[w]henever the issue arises, the fundamental factual inquire is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed... If a claim is amended to include subject matter,

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limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in the application" (*Id.*, § 2163.02). The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

When an explicit limitation in a claim "is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation." Hyatt v. Boone, 146 F.3d 1348, 1353, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998).

In the instant case, the independent claims have been amended to require that the "sample solution is free of metal particles". The disclosure as filed does not contain literal support for a method so limited. Although the specification contemplates the methods wherein biological materials are delivered through a cell membrane/wall or the skin without using metal particle carriers (see, e.g., the Abstract), a teaching that biological materials are delivered without using metal particle carriers is not the same as a teaching that the sample solution used in the method must be free of metal particles. Many solvents used to prepare biological samples comprise metal particles, such as iron, magnesium, etc., which do not have the properties of metal particle carriers for

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delivery of biological materials. As there is nothing in the disclosure that would lead one of skill in the art to conclude, at the time the patent application was filed, that the description requires that the solvent used in the method be free of all metal particles, support for the newly added claim limitation is not implicit in the disclosure as filed.

In view of the foregoing, the amendment of the claims introduces subject matter that was not present in the disclosure as originally filed. Therefore, the claims are properly rejected under 35 USC §112, first paragraph, as containing new matter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

> Daniel M Sullivan, Ph.D. **Primary Examiner** Art Unit 1636